4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0793]

Request for Nominations of Specific Drug/Biologic Product(s) That Could Be Brought Before the Food and Drug Administration's Pediatric Subcommittee of the Oncologic Drugs Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for product nominations.

SUMMARY: The Food and Drug Administration's (FDA) Office of Hematology and Oncology Products invites the public to suggest one or more specific drug or biologic products that could be brought before the December 4, 2012, Pediatric Subcommittee of the Oncologic Drugs Advisory Committee (ODAC). The number of drugs studied for use in pediatric patients is growing, and we see a reduction in off-label use. However, we would like to improve current and future pediatric product development by focusing on products whose development would benefit the most from the attention of an advisory committee. The company developing a product that is brought before the committee will be given the unique opportunity to present proposed pediatric studies in the United States, share their plans for global pediatric development, and hear discussions by the Pediatric Subcommittee on possible directions for their current or future pediatric oncology product development.

DATES: Nominations must be received by September 4, 2012, to receive consideration for inclusion. Nominations received after this date will receive consideration for future meetings of the Pediatric Subcommittee of the ODAC.

ADDRESSES: Email nominations to Christine.Lincoln@fda.hhs.gov, and please include the subject line "Suggested Product for 2012 Pediatric Oncology Subcommittee of ODAC."

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

The Food and Drug Administration (FDA) Advisory Committees are an important, transparent interface that allows the Agency to include the public in its decision-making processes. Significant public health and safety issues are brought before these committees for deliberation, and the meetings bring together both experts with state-of-the-art knowledge and members of the public with relevant personal experiences. This broad participation gives FDA a unique perspective as it seeks to assure the safety, efficacy, and security of FDA-regulated products.

Additional information about the prior November 2, 2011, Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee may be found on FDA's Web site at: http://www.fda.gov/AdvisoryCommittees/Calendar/ucm274396.htm.

Dated: August 2, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-19330 Filed 08/07/2012 at 8:45 am; Publication Date: 08/08/2012]